DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 12, 2015

Medagent Incorporated
Mr. Frank Menean
Managing Director
112 Corporate Drive, Unit 1
Portsmouth, New Hampshire 03801

Re: K143662
Trade/Device Name: Bissinger Monopolar Forceps and Cables
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 25, 2014
Received: December 23, 2014

Dear Mr. Menean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: **K**143622

Device Name:
Monopolar Forceps

Indications for Use:

The monopolar forceps and clamps are designed to grasp, dissect and coagulate tissue.
They must be connected to the monopolar output of an electrosurgical generator and must only be used with parameters for monopolar coagulation.
Do not exceed a maximum output of 2000 Vp of your generator.

Prescription Use __**X**___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K143662

VOLUME 006

510(k) Summary

DATE OF APPLICATION: 2014-01-07

Type of 510(K) submission: Traditional 510(K) submission

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1. Device Name

Trade Names: Bissinger Monopolar Forceps and Cables
Common Name: Monopolar Instruments and Accessoires
Classification Name: Electrosurgical cutting and coagulation device and accessories.

2. Classification Product Code / Subsequent Code

Device	Medical Specialty	Review Panel	Product Code	Device Class	Regulation Number
Monopolar Instruments and Accessoires	Part 878	General & Plastic Surgery	GEI	2	878.4400

3. Prior Submissions

There have been no prior submissions of the subject devices so far.

4. Predicate Device

Bissinger's Monopolar Forceps and Cables are substantially equivalent to the following predicate devices, already cleared by the FDA:

Predicate Device	510(k) Number	510(k) Holder
EGON FAULHABER Bipolar Forceps, Non Stick Bipolar Forceps and Monopolar Forceps	K101080	EGON FAULHABER Surgical Instruments Pinzetten
Black and Black Electrosurgical Cutting and Coagulation Forceps and Electrodes	K072124	Black & Black surgical Inc.
Olsen Medical Electrosurgical Cable/Adapters	K111262	Olsen Medical
Suffer Electrosurgical Cables	K073450	Suffer Medizintechnik GmbH

5. Description of the Device

Bissinger's Monopolar Forceps are used in various surgical applications. Therefore they are varying in size and build-up, though the general principle remains unchanged.
By using the firmly attached connecting cable, the monopolar forceps can be connected to high-frequency electrosurgical generators.

5.1. Monopolar Forceps

Monopolar Forceps are used for grasping, dressing and coagulating of tissue. They must be connected to a monopolar output of a high frequency generator by using the attached monopolar cable. The application of monopolar current and connection with a neutral electrode is mandatory.
Bissinger's monopolar forceps either have a straight or bayonet-shaped handle. They are equipped with a firmly attached connecting cable with dual spring connector.

5.2. Monopolar Cables

Bissinger Cables are a line of non-sterile, reusable Monopolar Cables fitting Erbe, Martin, Berchtold, Bovie, Valleylab, Codmann Electrosurgical units. They are designed to conduct electrical power from the output of a high frequency generator to the instrument.

6. Indications for Use

6.1. Monopolar Forceps

The monopolar forceps and clamps are designed to grasp, dissect and coagulate tissue. They must be connected to the monopolar output of an electrosurgical generator and must only be used with parameters for monopolar coagulation.

Do not exceed a maximum output of 2000 Vp of your generator

6.2. .Monopolar Cables

Cables for electrosurgery are designed to conduct electrical power from the output of a high-frequency electrosurgical generator to the electrosurgical instrument.
Do not exceed a maximum output of 6250 Vp of your generator.

7. Technological Characteristics

The technological characteristics of Bissinger's Forceps and Cables are identical or substantial equivalent as the previously cleared predicate devices stated in section 4 in terms of design, dimensions, intended use and materials.

8. Testing

Testing in order to proof safety and effectiveness of Bissinger's Monopolar Forceps and Cables has been performed according to recognized consensus Standards and results are conforming to the respective requirements.

8.1. Electrical Safety

The devices subject to this submission have been tested according to the requirements of EN 60601-1:2006 and EN 60601-2-2:2009.

8.2. Sterilization

The sterilization process has been validated under consideration of recognized standards.
Testing shows that the Products can be steam sterilized with a sufficient sterility assurance level by use of standard sterilization parameters.

8.3. Reprocessing

Reprocessability was tested and validated under consideration of recognized standards.

8.4. Manual cleaning

Manual cleaning validation was performed under consideration of recognized standards.

9. Biocompatibility

All requirements of biocompatibility are met through the composition of the used materials which demonstrate the appropriate levels of biocompatibility for its clinical use. The used materials are also used in many other medical devices and have an established history of safe use and biocompatibility outlined in ISO 10993-1.

10. Substantial Equivalence Summary / Conclusion

Based on available 510(k) information provided herein, Bissinger's Monopolar Forceps and Cables are considered substantial equivalent to the predicate devices in terms of indications for use, material, technology, design and performance specifications.

There are no differences between the devices which would raise new issues of safety or effectiveness.